ORIGINAL

MICROSTIMULATORS AND MICROTRANSDUCERS FOR FUNCTIONAL NEUROMUSCULAR STIMULATION

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Abstract

We are developing a new class of implantable electronic devices for a wide range of neural prosthetic applications. Each implant consists of a microminiature capsule that can be injected into any desired location through a 12 gauge hypodermic needle. Multiple implants receive power and digitally-encoded command signals from an RF field established by a single external coil. The first type of implant is a single-channel microstimulator equipped with capacitor-electrodes that store charge electrolytically and release it upon command as current-regulated stimulation pulses. We are also working on implants equipped with bidirectional telemetry that can be used to record sensory feedback or motor command signals and transmit them to the external control system.

In this quarter, we accumulated 90 days of successful accelerated life-testing on the first group of BION implants, which were built without the water-getter insert. This has prompted some redesign of the wetwell test system. We were successful in demonstrating the feasibility of using the getter material as a structural component of the implants, which maximizes the volume of the getter while reducing cost and simplifying manufacture of the implants. The ASICs for the BION stimulator and transceiver were thoroughly reworked and their layout checked according to design rules and schematic before submitting to MOSIS, which should deliver chips in early July. The first set of passive devices for long-term animal studies were implanted.

Implantable Devices

Soak test results

As of this writing, 3 of the 6 devices are still in soak testing started last quarter, with no significant change in their electrical performance after 3 months of temperature cycling (35 - 85◦C) and constant stimulation at maximal rated output (10 mA, 258 us, 50 pps). Two devices were removed from testing within 48 hours with visible moisture inside; one of these was among those with an apparent gross leak detected at the final bomb test during manufacture and another was mechanically cracked during frequent handling while the test apparatus was being debugged. A third removed device is still working, but it has always been sensitive to field strength, making it difficult to maintain coupling during the temperature cycling of the chamber and transmission coil.

While the implants have been relatively impervious to these test conditions, the test equipment has not. The tests have been interrupted frequently to deal with various problems such as thermal distortion of the wetwell and transmission coil, leakage of the saline from the wetwell chambers, and breakdown of the temperature controller on the oven. This has actually resulted in much more severe mechanical and thermal stress of the implants, as dried salt crystals accumulated around the electrodes and feedthroughs, hot devices at 85◦C were abruptly exposed to saline washes at room temperature and devices were repeatedly installed and removed from various chambers and baffles designed to improve the accuracy of output measures of current (see below). A proper

test under better-controlled conditions is expected in the next quarter on a batch of implants incorporating what now look like finalized assembly procedures, at least for the packaging and seals.

Getter test

In order to deal with the possibility of slow leaks of water vapor below the level of detectability in the production leak testing (<2 x 10^{-11} cc atm He/s, equivalent <1 x 10^{-11} cc atm H_2O/s), we intend to incorporate a slug of silicone with a 70% filler of anhydrous magnesium sulfate (see previous QPR#7). The larger the volume of this slug, the more water vapor it can absorb, preventing such water from condensing on the electronic circuitry. This raises the question of where to put it. In a previous QPR, we described the manufacture of a tubular getter that would act as a mechanical sleeve connecting the Pt-Ir tube to a small diameter version of the spring (20 mil o.d. equal to o.d. of Pt-Ir tube). (In the present design, the tube has a Pt-Ir washer welded on the end, which compresses a large diameter spring against the μPCB to make electrical contact.) This would eliminate the expensive Pt-Ir washer and its somewhat problematic YAG weld to the Pt-Ir tube and would avoid having to handle the spring as a loose part during capsule closure.

The critical question was whether heating of the Pt-Ir tube during the capsule closure seal (melting the glass capillary to the glass bead under CO2 laser) would damage

the getter sleeve. With the improved heat control of the laser and an improved collet that draws heat from the Ir electrode face, we were able to make hermetic glass seals without damaging the getter sleeve or the tiny spring inside it. In one dramatic demonstration of the effectiveness of the getter itself, we did this seal with a getter that had not been recently baked out. Although it appeared outwardly dry at room temperature, copious amounts of steam were emitted into the glass tube as the sleeve was heated during the capsule closure. A baked-out getter sleeve emitted no steam and showed no changes other than a slight darkening of some speckled surface contaminants.

Ceramic PCB Design

The small spring requires a modified interface at the end of the μPCB board (shown in figure 1), which now has indentations into which the large spring fits. We have also encountered some difficulty handling the somewhat soft and flexible epoxy PCB material and making thermosonic wire bonds directly to its metal pads. For these reasons, we have developed a design for a ceramic μPCB, which can be made in sheets using laser drilling and dicing procedures (see Figure). The circuit layout has been optimized for the new ASIC; both should be available in the next quarter.

Bomb tester

Conventional gross-leak detectors look for streams of bubbles emitted from putatively sealed devices that are placed in a liquid medium. A gross leak bubble detector device was designed for the BIONs using a technology developed by Medical Research Group, LLC.

In practice, the slow accumulation of low-leak-rate bubbles is limited by two problems. At the Ta end, bubbles are emitted from the sponge-like sintered Ta, which obscures any leaks that might come from these seals. Fortunately, these seals are the most reliable in the BION and are readily checked during manufacture while the capsule is open. At the Ir end, this method reliably detects leaks through the final YAG weld, which cannot be detected in any other way (there may be some false positive leaks detected, but we have had no missed leaks yet).

External Equipment

Revised wet-test wells and heater

Because of the various problems mentioned above, we are trying a new approach to the wetwells that are used to measure the electrical output of individual BIONs while they are being actively driven and temperature cycled. The new design, shown in Figure 3, uses individual test chambers made from the same polyethylene vials shown in Figure 4, in which the individual BIONs are now autoclaved and shipped. The temperature of the test chambers is controlled and can be cycled rapidly by circulating air around them and a resistive heating element. Wetwell temperature is controlled thermostatically via a probe in one of the saline-filled test vials.

The screw top of each individual vial has an o-ring seal which allows little water vapor loss for weeks at a time. The current-monitoring electrodes are sealed to the screw top and lowered into 5X hypertonic saline in the vial (to reduce the load seen by the BION implant so that it can reach its full output current without being limited by compliance voltage). The BION is held in the middle of the testwell by a sleeve equipped with a silicone gasket with a skirt that effectively divides the upper and lower half of the testwell into two electrically separate chambers. The output current generated by the BION must pass between its output electrodes in each of the two chambers, via the detecting electrodes in those chambers and a 100 Ω resistor in series with them. The

voltage across the resistor is monitored by the multiplexed A/D converter in the bedside controller. Thus, a 10 mA output pulse appears as a 1V pulse in the digitizer, which relays the measurement to the PC controlling the test system.

As of this writing, these test wells have been functioning well for about a week of constant stimulation and temperature cycling. The load resistance is low enough for the present BIONs to produce up to about 16 mA stimulation current before reaching their compliance voltage limits of 8V.

Large coil-driver for cats (IIT)

Large coil-drivers are presently being developed at IIT.

ASIC

MOSIS submissions

At the Mann Foundation preliminary checks of the layouts provided by layout houses revealed significant problems. Due to these findings, the original plan of going directly to a wafer was changed to a series of MOSIS runs. This decision turned out to be prudent as additional problems were found in the subsequent MOSIS run. By performing microsurgery and micropatching on the chip using ion beam devices, the chips were further analyzed. Future MOSIS runs are being planned verify the design and analysis. The high voltage output stages has turned out to be quite successful providing

18 volts of compliance with currents up to 40ma. The major problems remaining are with the demodulation of the incoming data.

Preclinical Regulatory Testing

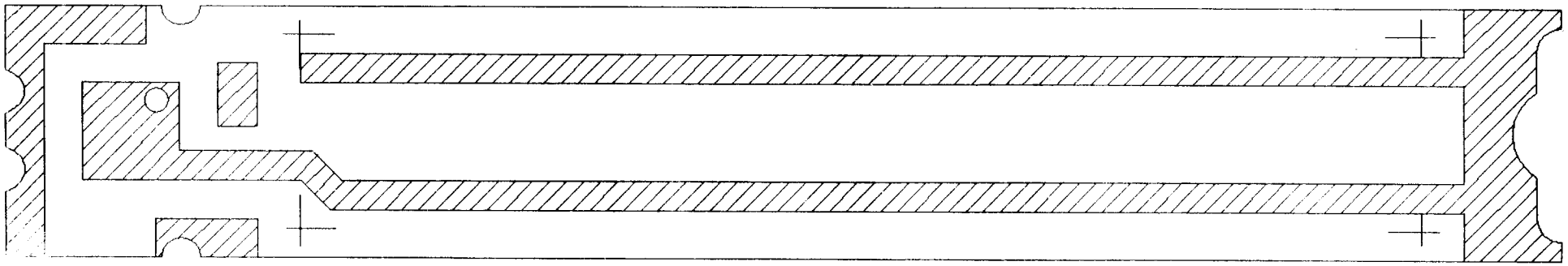
Long-term implants

We have completed implantation of one-third of the series of passive BIONs required for final demonstration of the biocompatibility of the completed implants. The complete series consists of 14 animals, each with a minimum of 2 "dummy" implants made with nonfunctional electronics but with the now-finalized external components and sealing methods. We have also included at least one BION in which the glass capsule is covered by a thin wall silicone sheath, which may further reduce the foreign body reaction to the devices in moving muscles and would capture any loose fragments in the unlikely event that an implant is shattered in situ. Also implanted are a silicone "bullet" of similar shape and a USP-approved negative control rod of polyethylene. The animals will be divided into groups for sacrifice and histological evaluation at 1, 3, 6 and 12 months after implantation.

Plans for Next Quarter

We expect to obtain initial results of the new wetwell testing apparatus on a set of 8 functional BIONs manufactured and tested under fully controlled conditions. We expect to have an initial evaluation of the histology from the 1 mo. chronic implants. The new ASICs will be tested and, if functional, will be built into working BIONs for further

qualification testing, using the ceramic substrate and small spring and getter system if possible. Coils and drivers will be optimized for the field strength and modulation requirements of the new ASIC and the application-specific requirements of our upcoming chronic animal and human trials.



Ceramic Carrier

COMPONENT SIDE

Figure 1

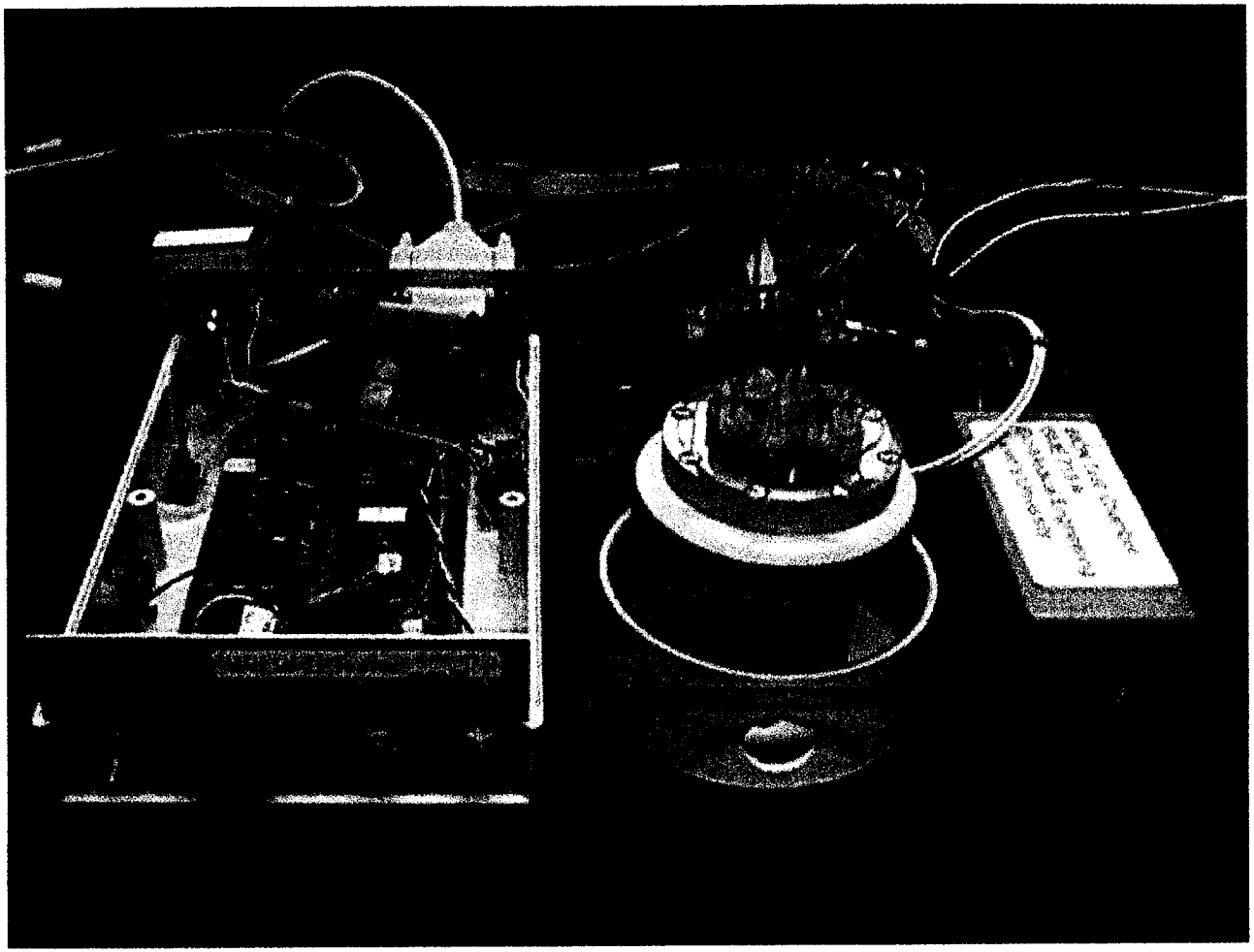
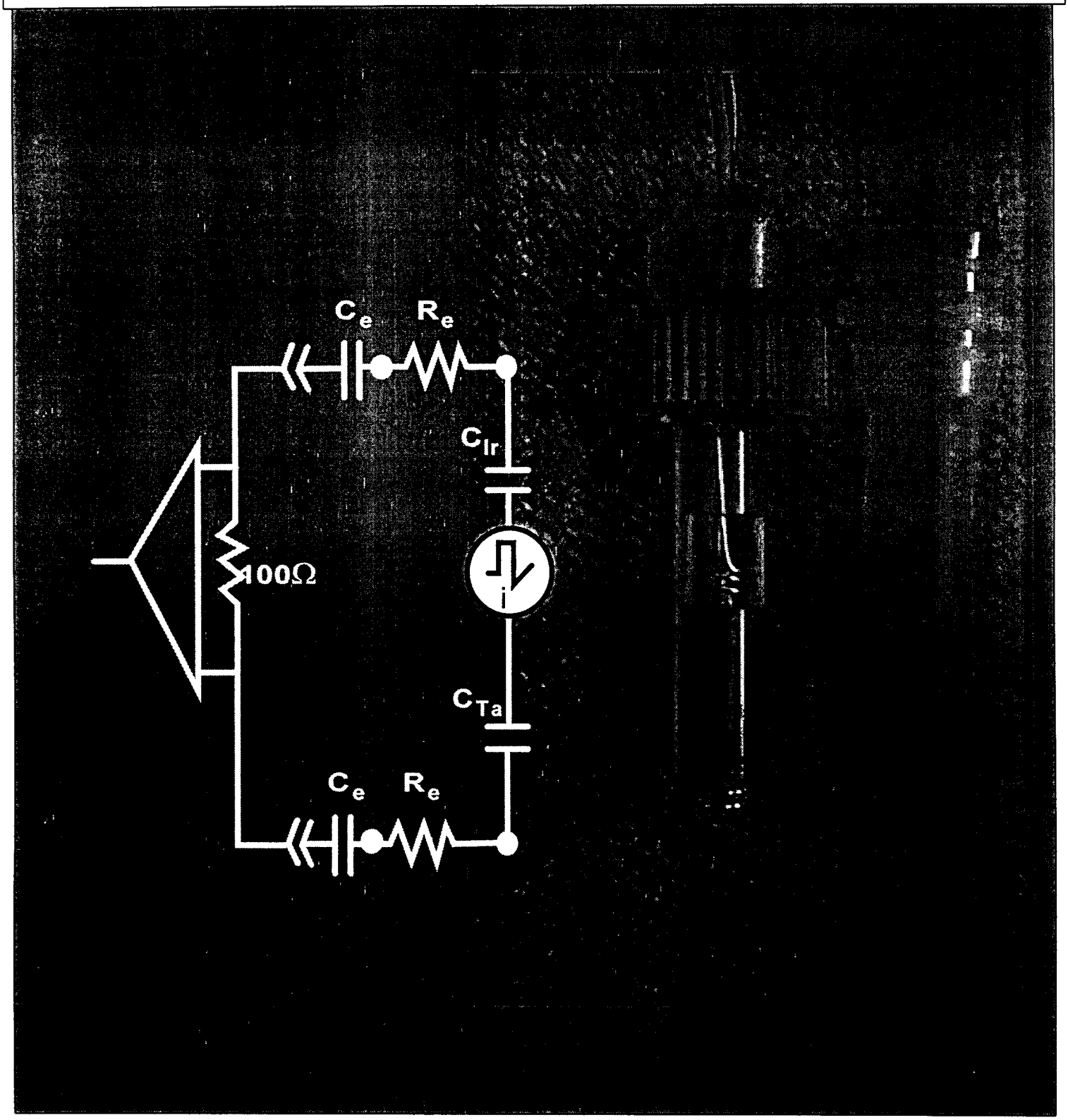
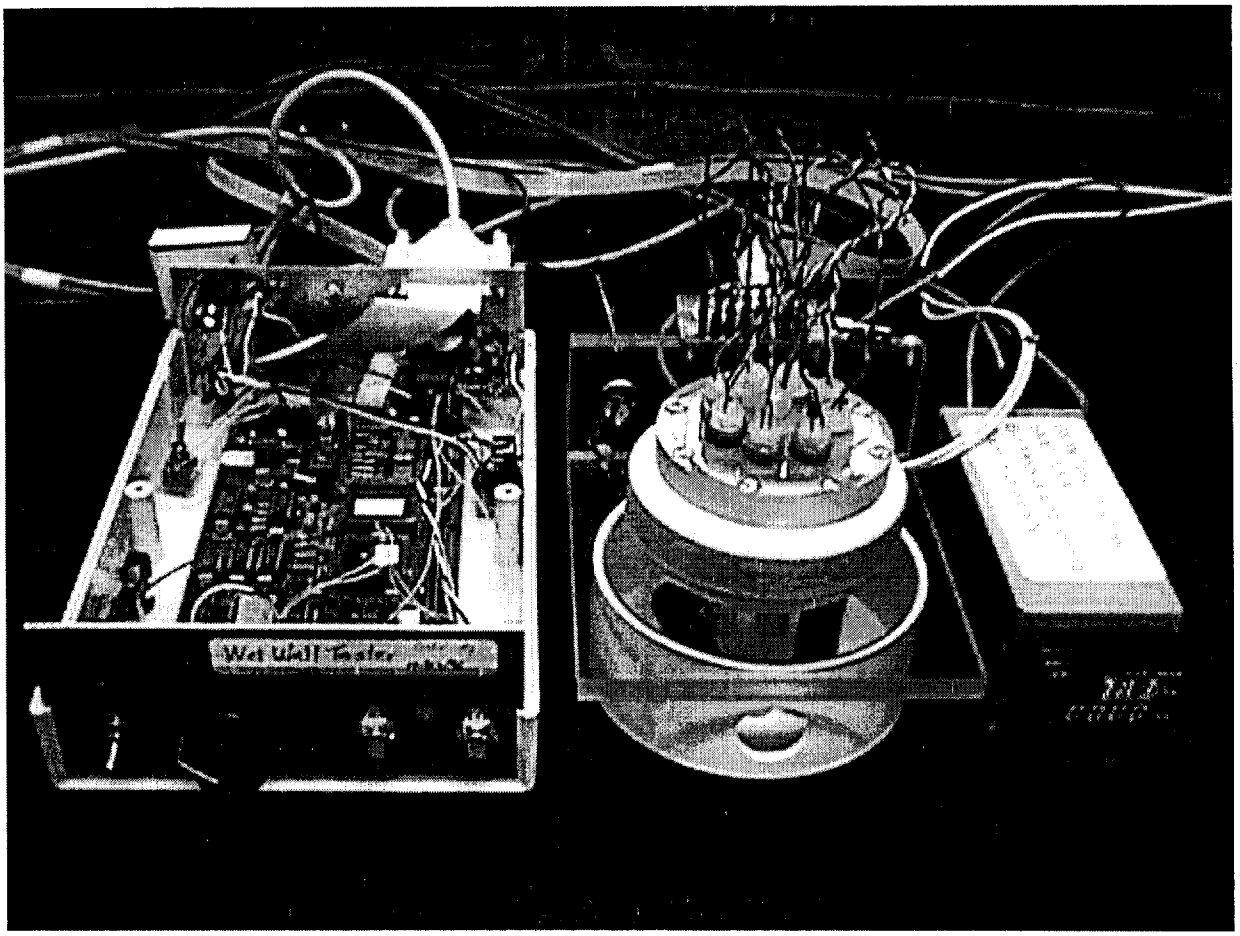


Figure 3A: Soak test chamber with BION in place between springlike recording electrodes. The BION acts as a current source with capacitive coupling from its output electrodes C_{Ir} and C_{Ta}, through the bridging saline R_e to the iridium coil detecting electrodes C_e, and through the precision 100Ω resistor. The voltage recorded across the resistor is digitized to measure stimulus pulses.





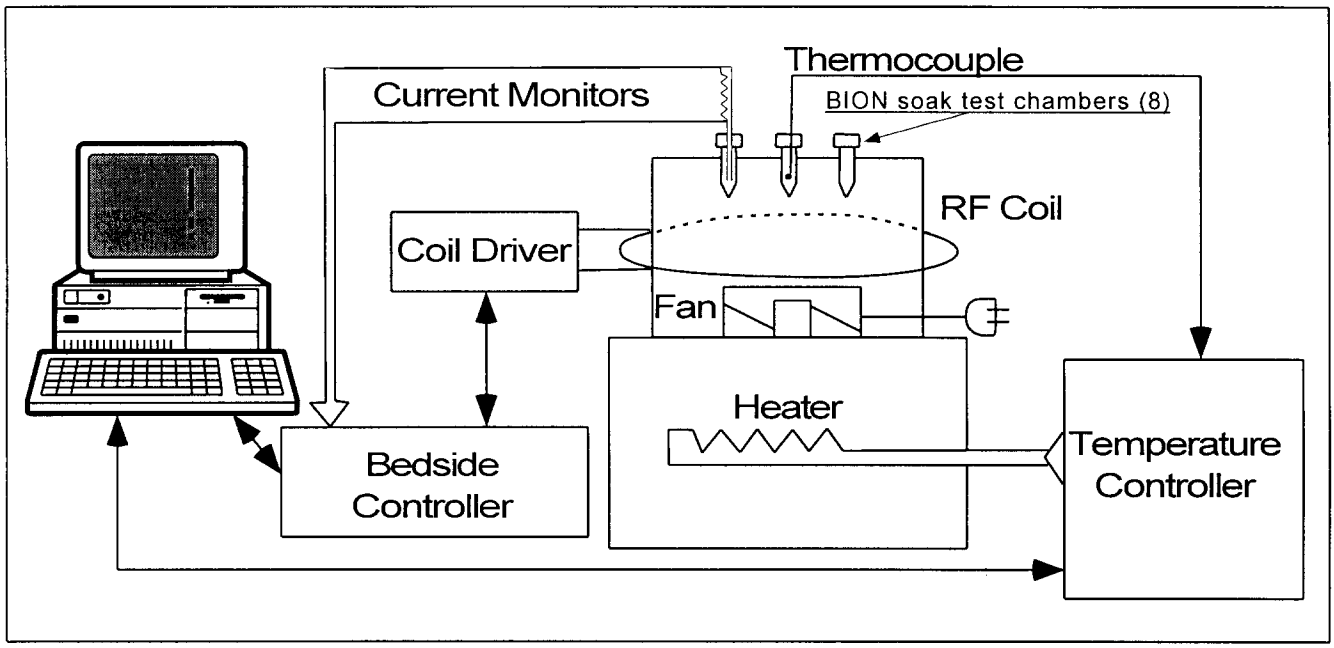


Figure 3B: Chronic wetwell test system operated by PC (custom Windows application) via serial ports to Bedside Controller and Temperature Controller. BIONs are placed in saline soak chambers equipped with recording electrodes (Fig. 3A) and are temperature cycled between 37°C and 77°C by a resistive Heater and air circulating Fan under thermostatic control. The Bedside Controller powers and commands the BIONs to produce output pulses via the Coil Driver and RF Coil and it monitors the output currents by digitizing the voltages across precision resistors. These values are accumulated in a spreadsheet and on-line graphical display by the PC.

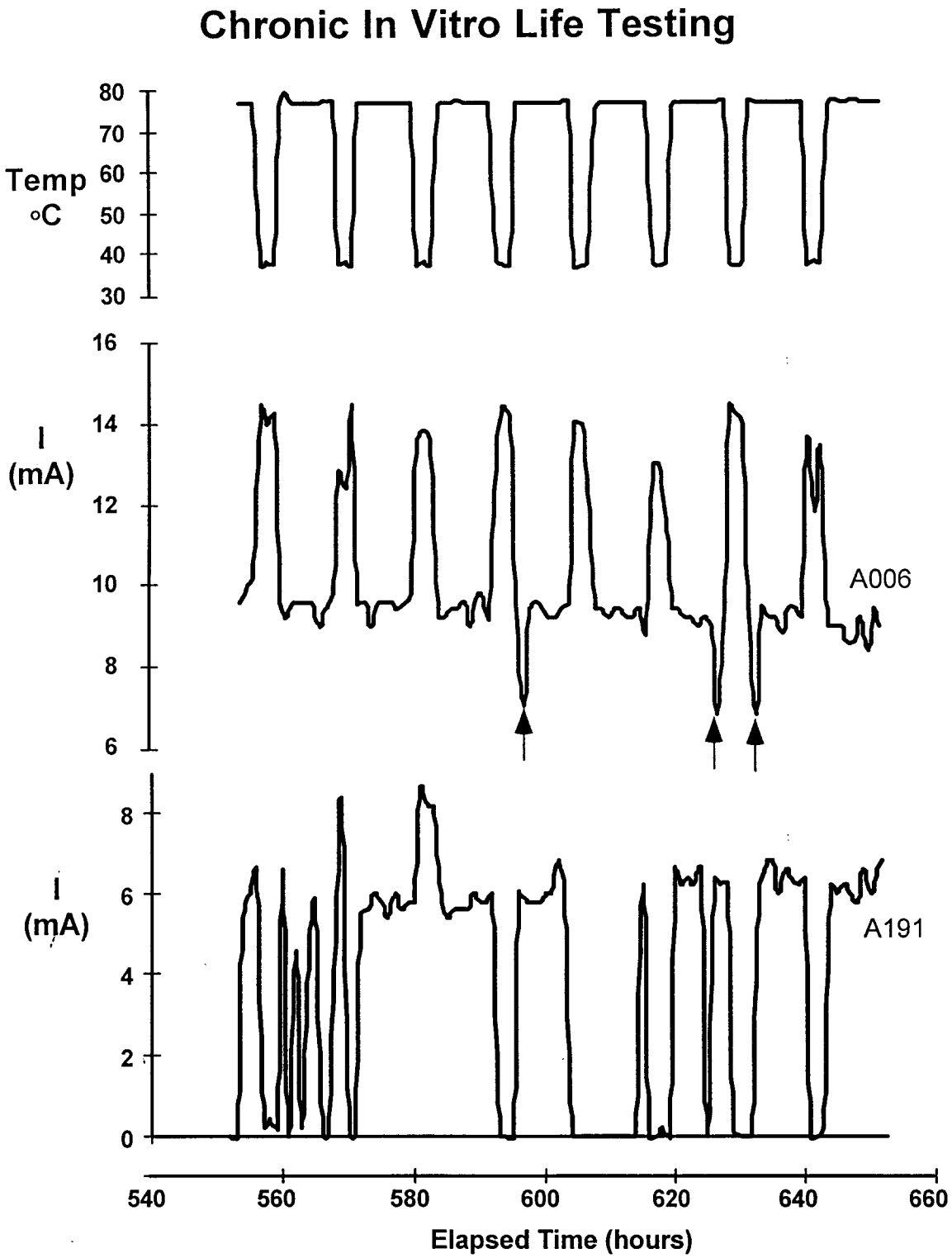


Figure 3C: Typical chronic test results during temperature cycling with continuous maximal rated output; hourly measures of output current plotted here for BION serial numbers A006 and A191. Device A006 was functioning normally, with output current decreasing at higher temperatures; occasional drops in output current (arrows) were due to air bubbles around the recording electrodes. Device A191 was failing due to moisture in the capsule. It tended to function only at the higher temperatures and then intermittently. At the lower temperatures, water condensation on the receiving coil shifted its resonant frequency so that it was no longer responsive to commands.

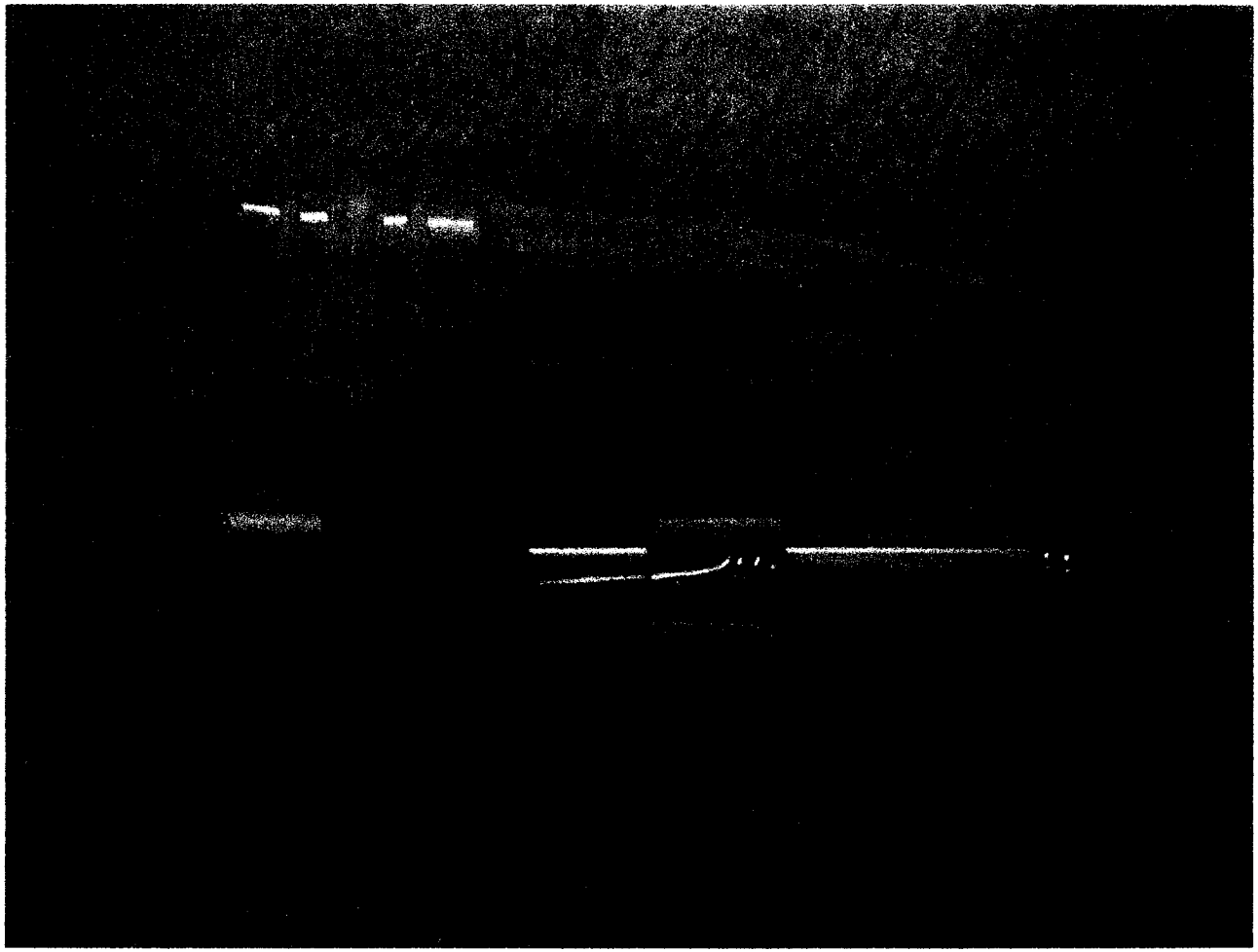


Figure 4